DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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DEPUTY ASSISTANT
COMMISSIONER FOR PATENTS

Food and Drug Administration
Rockville MD 20857

APR - 6 1992

Re: ACEL-IMUNE
Docket No. 92E-0115

#15

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,455,297 filed by Takeda Chemical Industries, Ltd. under 35 U.S.C. 156. The human biologic product claimed by the patent is the acellular pertussis toxoid component of ACEL-IMUNE, Product License Application (PLA) No. 87-0406.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the acellular pertussis vaccine.

The PLA was approved on December 17, 1991, which makes the submission of the patent term extension application on February 14, 1992, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Douglas P. Mueller
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Washington, D.C. 20036-8218